IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Richmond Division

DR. TIMOTHY BAXTER, Plaintiff, v. XAVIER BECERRA, in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, and CHRISTI A. GRIMM, in her official capacity as INSPECTOR GENERAL, DEPARTMENT OF HEALTH AND HUMAN SERVICES, Defendants.	Civil Action No. 3:23-cv-00092

MEMORANDUM IN SUPPORT OF PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

This case concerns whether the Secretary of the Department of Health and Human Services ("the Secretary") can impose an automatic, career-destroying penalty of exclusion from all federally funded health care programs for five years on Dr. Timothy Baxter, a physician with an established record of providing life-saving treatments to patients, based solely on pleading guilty to a single, strict-liability misdemeanor misbranding offense under the "Responsible Corporate Officer" ("RCO") doctrine. That doctrine, which has drawn intense criticism from courts and commentators, *see, e.g.*, *United States v. Facteau*, No. 15-CR-10076-ADB, 2020 WL 5517573, at *18 n.140 (D. Mass. Sept. 14, 2020); Martin Petrin, *Circumscribing the "Prosecutor's Ticket to Tag the Elite"—A Critique of the Responsible Corporate Officer Doctrine*, 84 Temp. L. Rev. 283, 324 (2012), allows the government to charge a corporate officer for a crime committed by a subordinate without any proof of intent (*mens rea*) or evidence of involvement in the underlying offense. For Dr. Baxter, that meant the government could criminally sanction him based solely on the actions of his subordinate—conduct of which Dr. Baxter was not even aware.

The relative wisdom of the RCO doctrine is not at issue here, nor is the propriety of Dr. Baxter's conviction, which he does not challenge. He has already served his punishment, which was, appropriately, probationary. What Dr. Baxter does challenge, however, is the Secretary's attempt to attach devastating sanctions—arguably more severe than those ordered by the district court—to that conviction. The Secretary claims that in doing so, his hands are tied because section 1128 of the Social Security Act supposedly *requires* that Dr. Baxter be excluded. But the statute, which limits the imposition of mandatory exclusion to only four categories of offenses, simply cannot bear such a reading. Moreover, the Secretary's assertion that Congress has mandated exclusion for Dr. Baxter is irreconcilable with agency precedent, which allows the Secretary, *at most*, discretion to consider excluding an individual convicted of his offense.

The Secretary's newfound interpretation not only parts ways with consistent agency precedent—in attaching severe sanctions to a strict liability offense, it also needlessly raises serious constitutional due process concerns. A proper reading of the statute, in line with both its clear text and intent, would avoid all of these pitfalls. Because the Secretary acted arbitrarily and capriciously in departing from agency precedent, and contrary to law in misconstruing the statute, his decision must be set aside.

BACKGROUND

I. REGULATORY & STATUTORY BACKGROUND

To protect Medicaid and other federally funded health care programs, Congress delegated to the Secretary discretionary authority to exclude a person from participation in federally funded health care programs if that individual satisfies any of seventeen specific criteria, including conviction for certain offenses. 42 U.S.C. § 1320a–7(b). Furthermore, exclusion is mandated after conviction for any of four types of offenses: those related to (1) the delivery of an item or service under Medicare or Medicaid; (2) patient abuse or neglect connected with the delivery of a health care item or service; (3) certain types of felony health care fraud; and (4) certain felony drug convictions. *Id*. § 1320a–7(a). The two categories of exclusion—mandatory and permissive—are mutually exclusive and thus do not overlap. *See Travers v. Sullivan*, 801 F. Supp. 394, 404 (E.D. Wash. 1992), *aff'd sub nom. Travers v. Shalala*, 20 F.3d 993 (9th Cir. 1994).

Given that federally funded health care programs "touch[ ] the lives of nearly all Americans," *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1808 (2019), the effect of exclusion is almost always severe. For example, HHS guidance makes clear that "an excluded individual may not serve in an executive or leadership role" of a pharmaceutical company where his salary can in any way be linked to a federally funded health care program. OFF. OF INSPECTOR GEN., U.S. DEP'T. OF HEALTH AND HUM. SERVS., *Updated Special Advisory Bulletin on the Effect of Exclusion from*

Participation in Federal Health Care Programs, at 7 (May 8, 2013), https://bit.ly/3I7Nppr (hereinafter "OIG Bulletin"). The prohibition applies "even if the administrative and management services are not separately billable." *Id.* Given the impossibility of disaggregating intangible services such as corporate leadership from the actual practice of medicine, the HHS exclusion guidance essentially means that if a pharmaceutical company manufactures or sells drugs that are reimbursed by a federally funded health care program, an excluded individual is ineligible for employment with that firm. *See* 42 CFR § 1001.1901(b)(1) ("No payment will be made by [a federal health care program] for any item or service furnished…[b]y an excluded individual or entity"). With annual federal spending on prescription drugs exceeding $378 billion, a pharmaceutical company would be hard-pressed to survive without selling medicines paid for with some amount of federal money. *See NHE Fact Sheet*, CTRS. FOR MEDICARE AND MEDICAID SERVS., (Feb. 17, 2023), https://go.cms.gov/3IJmQbW. Moreover, exclusion is not limited to one's former career field. Indeed, an excluded health care executive could not even work as an ambulance dispatcher where any care associated with the service is funded by the federal government. *See* OIG Bulletin at 7. Thus, exclusion effectively sounds a career death knell.

To the extent that a conviction meets the statutory requirement for exclusion, the Secretary has delegated the task of issuing and enforcing exclusion orders to the HHS Office of the Inspector General ("HHS-OIG"), 53 Fed. Reg. 12,993 (April 20, 1988), an office with a requested $453.8 million budget for fiscal year 2023 that operates largely independently of the HHS chain of command, OFF. OF INSPECTOR GEN., U.S. DEP'T. OF HEALTH AND HUM. SERVS., FISCAL YEAR 2023 JUSTIFICATION OF ESTIMATES FOR CONGRESS, at 2 (2022), https://bit.ly/3XAgvUf.

Once HHS-OIG makes an internal determination about whether exclusion is appropriate, an administrative process begins. First, HHS-OIG issues a notice of exclusion explaining the effective date and the minimum period of exclusion. 42 U.S.C. § 1320a–7(c). Then, the affected

person may request a hearing before an administrative law judge within HHS. *See* 42 C.F.R. §§ 1001.2007, 1005.2. HHS's Departmental Appeals Board ("DAB") may examine an adverse decision from an ALJ if a party makes a timely appeal. 42 C.F.R. § 1005.21. Unfortunately, exclusions are seldom reversed by the agency.

II. DR. BAXTER'S EXCLUSION UNDER THE SOCIAL SECURITY ACT

A. Dr. Baxter and Indivior

Dr. Timothy Baxter is a medical doctor whose vocation is saving and improving lives. He began his career as a physician in a surgical ward. After years of caring for individual patients, Dr. Baxter turned his focus toward helping people on a broader scale—working as a pharmaceutical clinical researcher. Until recently, Dr. Baxter served as a consultant developing treatments for cocaine overdose, weaponized fentanyl, and women's health issues, among other projects. But for the better part of the past two decades, he was Indivior's chief medical officer.[1]

Indivior's biggest impact has been the production of two prescription drugs geared towards tackling the opioid crisis and helping people suffering from opioid use disorder resume their lives. These lifesaving drugs are called Suboxone and Subutex. AR542. Both drugs contain buprenorphine, are distributed in tablet form, and are approved by the Food and Drug Administration ("FDA") as Schedule III drugs for the maintenance therapy of opioid addiction. AR540. However, unlike Subutex, Suboxone combines buprenorphine with naloxone and is much less attractive to those who wish to abuse buprenorphine because naloxone precipitates withdrawal symptoms when snorted or injected. *See* AR540.

[1] In December 2014, RBP was demerged from its parent company, Reckitt Benckiser Group, and renamed Indivior. Concurrent with or shortly after the demerger, Dr. Baxter's title changed from Global Medical Director to Chief Medical Officer.

In the two decades since the FDA approved Suboxone for use outside of a clinical setting, medication-assisted treatment has become a critical weapon in the fight against the opioid epidemic. *See* AR540. Prescriptions such as Suboxone have played a crucial role in saving lives from the scourge of drug abuse. In fact, public health officials have praised the benefits of Suboxone, noting that they have "witnessed people with addiction rebuild relationships with family and friends" as a direct result of the drug. Sebastian Tong, et al., *Tong, Melton and Neuhausen column: Why offering medication-assisted treatment is essential to combating Virginia's addiction crisis*, RICHMOND TIMES DISPATCH (Sept. 5, 2016), https://bit.ly/3pJktfX. They have also seen those suffering from Opioid Use Disorder "start meaningful employment, reduce criminal activity, and obtain steady housing with the aid of these medications." *Id*.

In 2010, Indivior brought a new drug to market: a film version of Suboxone. Each dose of Suboxone Film is individually packaged and taken by placing a strip of film under one's tongue where the medication dissolves. *See* AR541. By 2011, Suboxone Film and Suboxone Tablet were both available through the Massachusetts Medicaid program, MassHealth. Suboxone Film, however, was not a "preferred drug" on the formulary and thus had restrictions on approval for reimbursement. AR542.

Like other drugs, Suboxone carries a risk to children who take it by accident. Suboxone Film became an attractive alternative to tablets packaged in multi-dose bottles. When scientifically significant data reflecting this benefit became available, one of Dr. Baxter's subordinates, Dr. Jane Ruby, shared it with MassHealth. AR544. On one occasion in October 2012, however, Dr. Ruby shared inaccurate data with the agency. AR545. According to Massachusetts-specific data collected by the Researched Abuse, Diversion, and Addiction-Related Surveillance System ("RADARS"), the rate of unintended pediatric exposures was lower with Suboxone Film compared to Suboxone Tablets, confirming Indivior's expectations. AR544. Surprisingly,

however, the data indicated that the risk of pediatric exposure for Subutex Tablets was even lower than for Suboxone Film. AR544. Before sharing this data, however, Dr. Ruby decided to add together the unintended childhood exposure rates for Suboxone Tablets and Subutex Tablets in an apparent (but mistaken) attempt to compare all tablets with Suboxone Film. AR545. As a result, the data Dr. Ruby shared suggested that Suboxone Film had the lowest rate, when in fact Subutex Tablets had the lowest overall rate of unintended pediatric exposure. AR545. Although Dr. Baxter was copied on correspondence containing the raw data collected by RADARS, he was not involved in combining the data or transmitting that data to MassHealth. *See* AR544–45. While Dr. Ruby forwarded her transmission after the fact, Dr. Baxter had no reason to suspect the calculation was incorrect—Dr. Ruby informed Dr. Baxter that she planned to obtain combined tablet data from RADARS, and she did not reveal to him that she had made the calculations herself. AR544–45.

In November 2012, Dr. Ruby shared a peer-reviewed and published chart depicting accurate and unaltered nation-wide data, also from RADARS, comparing unintended pediatric exposures between Suboxone Film and Suboxone Tablets alone. AR545–46. Dr. Baxter was not copied on that email. AR546. In contrast to the Massachusetts-only data, the national data did not mention Subutex Tablets.[2] AR545.

Just one month after Dr. Ruby submitted the chart containing accurate national data, MassHealth issued a prescriber letter stating that MassHealth would adjust its approval criteria with respect to prior authorization requests submitted on behalf of "those [MassHealth] members prescribed Suboxone who live in households with children less than six years of age." AR440.

[2] A subsequently published analysis of national data would later confirm, as expected, that Suboxone Film did in fact have a lower rate of exposure than both Suboxone Tablets and Subutex Tablets. The rate of exposures to Subutex was, however, lower than the Suboxone Tablet rate. AR485 (*citing* EJ Lavonas et al., *Root Causes, Clinical Effects, and Outcomes of Unintentional Exposures to Buprenorphine by Young Children*, 163 Journal of Pediatrics 1377 (2013)).

As the basis for this expansion of coverage, MassHealth cited the accurate, nationwide published RADARS data "document[ing] a greater unintentional exposure risk of buprenorphine/naloxone tablets than with that of the film in children 0 to five years of age." AR440. MassHealth did not cite or appear to rely upon the inaccurate data provided by Dr. Ruby. *See* AR440.

In December 2015, Indivior sent MassHealth a correction letter regarding the misleading pediatric exposure data shared previously. AR547. Despite the correction, and just one month after Indivior flagged Dr. Ruby's inaccurate submission, MassHealth promoted Suboxone Film to be the "preferred buprenorphine/naloxone product" for all MassHealth beneficiaries. AR447. After this change, "[a]ll other formulations [would] require prior authorization" even though Suboxone Film generally would not. AR447. Suboxone Film remains the preferred buprenorphine/naloxone product for all MassHealth beneficiaries despite the years of investigation by DOJ that led to Dr. Baxter's misdemeanor misbranding conviction. *See* AR519.

B. Government Prosecution

Dr. Baxter paid the price for Dr. Ruby's misrepresentations. Federal prosecutors charged Dr. Baxter with RCO misdemeanor misbranding in violation of the Food, Drug, and Cosmetic Act ("FDCA"). AR547. Specifically, the Information charged Dr. Baxter with violating 21 U.S.C. § 331(a), which prohibits "[t]he introduction or delivery for introduction into interstate commerce of any . . . drug . . . that is adulterated or misbranded." Misbranding occurs when, among other things, a drug's "labeling is false or misleading in any particular." *Id*. § 352(a). Misbranding is punishable by a maximum of one year's imprisonment and a $1,000 fine. *Id*. § 333(a)(1). Dr. Baxter pled guilty, AR549–58, and was convicted, AR561. The Information did not charge Dr. Baxter with criminal intent, nor did his guilty plea suggest otherwise. Likewise, the court did not find that Dr. Baxter had caused MassHealth any harm or order Dr. Baxter to pay any forfeiture or restitution. *See* AR565.

Dr. Baxter's conviction, which he is not challenging, was premised on the heavily criticized RCO doctrine. *See* AR547. That doctrine allows the government to charge corporate officials in a "position of authority" who fail to prevent or correct a violation of the FDCA. *See United States v. Park*, 421 U.S. 658 (1975). In the case of Dr. Baxter, DOJ charged him with misdemeanor misbranding under a theory that the chart shared by Dr. Ruby depicting accurate information about the national rate of accidental childhood exposures to Suboxone Tablets versus Suboxone Film was misleading labeling in light of her prior inaccurate statements about state-level data. AR545–46.

Under the RCO doctrine, Dr. Baxter was not required to have committed an FDCA violation himself, nor did he even need to have intent concerning the misbranding to be prosecuted. *See Meyer v. Holley*, 537 U.S. 280, 287 (2003) (RCO doctrine imposes an "unusually strict rule[]"). In fact, the record shows Dr. Baxter was not copied on emails central to the misbranding. AR544–45. Rather, the government charged Dr. Baxter and Indivior Chief Executive Officer Shaun Thaxter with misdemeanor offenses simply because they held positions of authority over Dr. Ruby, who was never prosecuted herself. AR547; *United States v. Thaxter*, No. 1:20-cr-0024 (W.D. Va. June 30, 2020), ECF No. 1.

Dr. Baxter was sentenced to one year of probation. Although part of the year was to be spent in home confinement, AR564, the sentencing court ensured that he would be allowed to "leave to engage in any of the aspects of his employment . . . ." AR616. As the court acknowledged, "[t]he government I don't believe thinks that particularly in relation to the particular offense of which Dr. Baxter has pled guilty that Dr. Baxter will commit future crimes." AR611–12. The court with supervision responsibilities proceeded under the same assumption, authorizing Dr. Baxter to travel outside the district "for matters related to his employment or his licensure." AR78, 483 (citing Order, *United States v. Baxter*, No. 3:21-cr-0008 (E.D. Va. Feb. 3,

2021), ECF No. 6). Notably, Dr. Baxter was not required to pay any form of restitution, AR561–66, reflecting that Dr. Baxter's misdemeanor offense did not result in loss or harm to MassHealth.

C. Dr. Baxter's Exclusion

Although he had parted ways with Indivior, Dr. Baxter was ready to move forward with his life following his guilty plea. Unfortunately, the Secretary had other ideas. Despite the district court's decision to impose a sentence that would allow Dr. Baxter to continue his important work, *see* AR616, on March 31, 2021, HHS-OIG notified Dr. Baxter that he was subject to *mandatory* exclusion under section 1128(a), AR024 n.8. Because that exclusion became effective without giving Dr. Baxter prior notice or an opportunity to be heard, Dr. Baxter filed a complaint in the U.S. District Court for the Eastern District of Virginia challenging the decision as violating his constitutional right to due process. AR024 n.8. Under a settlement agreement with Dr. Baxter, HHS-OIG withdrew the exclusion decision and agreed that Dr. Baxter should be allowed ninety days to respond to any future notice. AR024 n.8.

On May 27, 2021, HHS-OIG issued a new letter, which notified Dr. Baxter that the Secretary intended to exclude him from participation in all federal health care programs pursuant to 42 U.S.C. § 1320a-7(a). AR779.

On August 30, 2021, Dr. Baxter filed a 22-page response with nearly 100 pages of exhibits supporting his position. *See* AR470–491. Among the exhibits was testimony from MassHealth's Pharmacy Director, Dr. Paul Jeffery, noting that Suboxone Film is an important drug prescribed to MassHealth patients to this very day. The letter sought a meeting with HHS-OIG officials to "better understand and address HHS-OIG's basis for imposing mandatory exclusion . . . ." AR471. Despite the extensive record, on September 30, 2021, HHS-OIG issued a one-page letter informing Dr. Baxter that the agency would impose a mandatory exclusion for the minimum statutory period of five years. AR535. Now in his sixties, Dr. Baxter received the letter as an early and unwelcome

notice that effectively ended his career in health care. Pursuant to the Department's rules, Dr. Baxter appealed his exclusion to an Administrative Law Judge ("ALJ"), AR051–92, and then to the Departmental Appeals Board ("DAB"), AR246–289, each of which affirmed the decision, AR001, 018.

In affirming Dr. Baxter's exclusion, the Secretary failed to justify how HHS-OIG could impose a mandatory exclusion on Dr. Baxter after the Secretary had acted pursuant to his permissive authority in imposing exclusions on others convicted of the very same RCO misdemeanor offense. Specifically, in *Friedman v. Sebelius*, 686 F.3d 813, 816 (D.C. Cir. 2012), the D.C. Circuit had affirmed a permissive exclusion where "[a]ppellants pleaded guilty to misdemeanor misbranding, in violation of 21 U.S.C. § 331(a) and § 333(a)(1) . . . [u]nder the 'responsible corporate officer' (RCO) doctrine." Although the Secretary agrees that mandatory and permissive exclusion are mutually exclusive categories, the Secretary could not explain why a different approach was warranted here.

The Secretary likewise failed to adequately address the fact that HHS-OIG had *never* interpreted mandatory exclusion to reach misdemeanor misbranding offenses in the absence of a restitution or forfeiture order showing a nexus between the offense and delivery of an item or service under Medicare or a state health care program—*i.e.*, that the offense was "related to the delivery of an item" for purposes of section 1128(a)(1). The DAB's consideration of the facts supposedly supporting such a nexus was similarly suspect. Contrary to the Secretary's ultimate conclusion that Dr. Ruby's statements had caused MassHealth to grant preferential status to Suboxone Film, the record evidence before the DAB showed that the agency's decisions were unaffected by the misbranding for which Dr. Baxter was held responsible. *See* AR267–71. For example, the record makes clear that Suboxone Film was covered by the MassHealth program prior to the misbranding. AR542. And the MassHealth order making it easier for certain

MassHealth beneficiaries to obtain Suboxone Film cited only accurate, nation-wide data to justify the decision. AR440. Moreover, MassHealth promoted Suboxone Film to be the preferred product in its category for all MassHealth beneficiaries *after* Indivior informed MassHealth about Dr. Ruby's bad math. AR522. And even if MassHealth's decisions were affected by the misbranding, the Secretary presented no evidence showing that these decisions or the misbranding itself had caused MassHealth to cover any additional treatments or, if MassHealth had done so, that the treatments could not have been approved absent the MassHealth order expanding coverage.

Despite both the law and record evidence demonstrating the exclusion was improper, on September 30, 2022, the DAB issued its ruling, making it the final decision of the Secretary. AR018. Dr. Baxter was therefore forced to challenge his exclusion in this Court.

III. STATEMENT OF UNDISPUTED MATERIAL FACTS[3]

1. Dr. Timothy Baxter "enter[ed] a plea of guilty to Count 1 of the Information." AR549; *see* AR561; *see also* Answer ¶¶ 5, 53.

2. Count 1 of the Information "charge[d] [Dr. Baxter] under the Responsible Corporate Officer doctrine with the misdemeanor offense of causing the introduction or delivery for introduction into interstate commerce of a drug that is misbranded, in violation of 21 U.S.C. §§ 331(a) and 333(a)(1)." AR549; *see also* Answer ¶ 5.

3. Dr. Baxter's plea was based on "the facts set forth in the Information." AR550.

4. The Information alleged that the single misbranding occurred through the confluence of two acts. First, Indivior's Medical Affairs Manager, Dr. Jane Ruby, sent MassHealth an email in which she added together the unintended childhood exposure rates for Suboxone

[3] While there can be no material factual dispute here because review is confined to the administrative record, *see* 5 U.S.C. § 706, Dr. Baxter provides this abridged summary of key material facts both to assist the Court and to comply with Local Rule 56(B).

Tablets and Subutex Tablets in an apparent attempt to compare all tablets with Suboxone Film. AR545–46. Second, she emailed a chart from a study that was also used in an Indivior promotional brochure (and thus labeling under the FDCA) containing truthful information about the national rate of accidental childhood exposures to Suboxone Tablets versus Suboxone Film, which was rendered misleading in light of her prior email combining state-level data for Suboxone Tablets and Subutex Tablets. AR545–46.

5. The Information did not allege that Dr. Baxter personally misbranded any drugs; rather, his criminal liability stemmed from his position as a "responsible Indivior executive." AR547; *see also* Answer ¶¶ 5, 53.

6. The Information also did not allege that Dr. Baxter had any intent to misbrand any drugs. AR538–47.

7. The sentencing court did not require Dr. Baxter to pay restitution or forfeit any money. AR561–66; *see* Answer ¶ 39.

8. After rescinding the initial exclusion decision that was given without prior notice, HHS-OIG notified Dr. Baxter that it intended to subject him to mandatory exclusion pursuant to 42 U.S.C. § 1320a-7(a). AR779; Answer ¶¶ 6, 46.

9. HHS-OIG subsequently imposed a mandatory exclusion for the minimum statutory period of five years. AR535; Answer ¶ 6.

10. Dr. Baxter exhausted his administrative remedies by challenging his exclusion before the ALJ, AR051–92, and the DAB, AR246–289.

11. Among other things, Dr. Baxter argued that the Secretary lacked authority to subject him to mandatory exclusion and that the exclusion decision was arbitrary and capricious. AR258–84.

12. The Secretary upheld Dr. Baxter's exclusion. AR018–50.

SUMMARY JUDGMENT STANDARD

In reviewing an agency action pursuant to the Administrative Procedure Act ("APA"), a court will set aside the action "if the court finds that the agency action was 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" *PhotoCure ASA v. Dudas*, 622 F.Supp.2d 338, 343 (E.D. Va. 2009) (quoting 5 U.S.C. § 706(2)(A)). Because the APA "confines judicial review of executive branch decisions to the administrative record of proceedings before the pertinent agency . . . there can be no genuine issue of material fact in an APA action, and the legal questions presented in [an APA] action are therefore ripe for resolution on cross-motions for summary judgment." *Shipbuilders Council of Am. v. U.S. Dept. of Homeland Sec.*, 770 F.Supp.2d 793, 802 (E.D. Va. 2011) (citing 5 U.S.C. § 706; *Camp v. Pitts*, 411 U.S. 138, 142 (1973)). "[W]hen a party seeks review of agency action under the APA, the district judge sits as an appellate tribunal," and "[t]he entire case on review is a question of law." *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001) (internal marks omitted).

ARGUMENT

I. THE SECRETARY LACKS STATUTORY AUTHORITY TO IMPOSE CAREER-ENDING PENALTIES ON DR. BAXTER BASED UPON HIS OVERLY BROAD CONSTRUCTION OF MANDATORY EXCLUSION.

In this case, the Secretary claims authorization from Congress to impose an automatic, career-destroying penalty of exclusion from all federally funded health care programs for five years on Dr. Baxter, a physician with an established record of providing life-saving treatments to patients, based solely on pleading guilty to a single, strict-liability misdemeanor misbranding offense under the RCO doctrine. But even if there is "a colorable textual basis" for the Secretary's claim that Congress meant to authorize this extraordinary power, "separation of powers principles and a practical understanding of legislative intent" "ma[k]e it very unlikely that Congress ha[s] actually done so." *West Virginia v. EPA*, 142 S. Ct. 2587, 2609 (2022); *see Nat'l Fed'n of Indep.*

Bus. v. OSHA, 142 S. Ct. 661, 665 (2022). Far from providing clear authorization, section 1128(a) is best read to *foreclose* mandatory exclusion for a strict-liability misdemeanor misbranding offense under the RCO doctrine. And the structure of section 1128—particularly, the broad scope of permissive exclusion under section 1128(b)—confirms that the Secretary's interpretation here was erroneous, and that Dr. Baxter's mandatory exclusion must be vacated.

A. The Secretary's Claimed Authority Presents Major Questions.

Under the major-questions doctrine, courts require "clear congressional authorization" to uphold an agency's claim to significant power. *Nat'l Fed'n of Indep. Bus.*, 142 S. Ct. at 665. That principle applies here because, at a minimum, the Secretary's exclusion decision "implicates a substantial constitutional question" concerning Dr. Baxter's freedom to pursue his chosen occupation. *Merck & Co. v. United States Dep't of Health & Hum. Servs.*, 962 F.3d 531, 540 (D.C. Cir. 2020) (holding HHS rule triggered major questions doctrine where it potentially infringed constitutional rights).

Dr. Baxter's right to pursue his career as a medical professional is guaranteed by the due process clause of the Fifth Amendment. "Liberty under law extends to the full range of conduct which the individual is free to pursue, and it cannot be restricted except for a proper governmental objective." *Bolling v. Sharpe*, 347 U.S. 497, 499–500 (1954). Due process thus protects Dr. Baxter's right "to engage in any of the common occupations of life," *Elhady v. Kable*, 993 F.3d 208, 219 (4th Cir. 2021), including his desire "to follow a chosen profession free from unreasonable governmental interference," *Greene v. McElroy*, 360 U.S. 474, 492 (1959). For that reason, due process also requires that "penalties" for strict liability crimes be "relatively small," so that "conviction does no grave damage to an offender's reputation." *Morissette v. United States*, 342 U.S. 246, 256 (1952); *see Liparota v. United States*, 471 U.S. 419, 426 (1985) ("criminal offenses requiring no *mens rea* have a 'generally disfavored status'").

The Secretary's unwarranted exclusion of Dr. Baxter threatens his fundamental rights and is disproportionate to his offense. The Fourth Circuit has for forty years recognized that the Fifth Amendment guarantee of due process protects a physician's "right in continued participation in the [M]edicaid program." *Bowens v. North Carolina Dep't of Hum. Res.*, 710 F.2d 1015, 1018 (4th Cir. 1983); *see Ram v. Heckler*, 792 F.2d 444, 447 (4th Cir. 1986) (holding doctor's "expectation of continued participation in the [M]edicare program is a property interest protected by the due process clause of the fifth amendment"). And the underpinnings for the Fourth Circuit's recognition of that right have only grown stronger over the ensuing decades, as today federal health care programs account for an even greater share of health care spending. *Table 5 National Health Expenditures by Type of Sponsor: Calendar Years 1987–2021*, available at *National Health Expenditure Data: Historical*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Dec. 21, 2021), https://go.cms.gov/3F2wJiC.[4]

Furthermore, HHS guidance warns excluded individuals that they are prohibited not only from providing "direct patient care," but also from "serv[ing] in an executive or leadership role" and even from providing "other types of administrative and management services, such as health information technology services and support" at any company that furnishes items or services payable by federal health care programs. OIG Bulletin at 7–8. That, of course, is practically every

[4] In *Friedman*, the D.C. Circuit concluded that permissive exclusion from federal health care programs for a strict liability offense did not offend due process. 686 F.3d at 823–24. The court did not address whether the answer would be different in the context of mandatory exclusion, which prohibits the Secretary from accounting for mitigating circumstances. Furthermore, the Fourth Circuit's recognition that a physician's expectation of continued participation in federal health care programs implicates a due process right, coupled with the growth of federal health care programs since *Friedman* was decided, make *Friedman*'s rejection of due process concerns untenable here.

health care company.[5] The breadth of federal health care spending combined with the extensive effects of an exclusion effectively renders an excluded individual unemployable in the medical profession. This serious threat to constitutional rights necessarily presents a question of "major significance." *Merck & Co.*, 962 F.3d at 540; *see also Williams v. Kincaid*, 45 F.4th 759, 774 n.8 (4th Cir. 2022) (avoiding statutory interpretation that would require decisions of constitutional issues).

The threat to constitutional rights is not the only measure revealing "the breadth of the Secretary's asserted authority" that implicates the major questions doctrine. *Merck & Co.*, 962 F.3d at 541. Also significant are "the implications of the authority claimed" by the Secretary. *Ibid.*; *see Gonzales v. Oregon*, 546 U.S. 243, 248–49, 268 (2006) (rejecting the argument that Congress implicitly delegated the authority to "prohibit doctors from prescribing regulated drugs for use in physician-assisted suicide" in part because, under the Government's theory, the Attorney General would have broad power to "decide whether *any* particular drug may be used for any particular purpose," and whether "a physician who administers any controversial treatment could be" punished) (emphasis added).

The implications counsel caution here. Under the broad construction of section 1128(a)(1) the Secretary adopted below, a misdemeanor misbranding conviction would "relate[ ] to" the

[5] According to the Kaiser Family Foundation, 99 percent of non-pediatric doctors accept Medicare. *See* Nancy Ochieng et al., *How Many Physicians Have Opted-Out of the Medicare Program?*, KAISER FAMILY FOUND. (Oct. 22, 2020), https://www.kff.org/medicare/issue-brief/how-many-physicians-have-opted-out-of-the-medicare-program/ ("Only 1 percent of non-pediatric physicians have formally opted-out of the Medicare program"). And virtually every hospital in the country accepts federal health care payments of some sort. *See Do All Hospitals Accept Medicare?*, UNITED MEDICARE ADVISORS, https://unitedmedicareadvisors.com/do-all-hospitals-accept-medicare/ (last visited Mar. 8, 2023) ("Generally, the hospitals that do not accept Medicare are Veterans Affairs and active military hospitals (they operate with VA and military benefits instead)"). Under HHS guidance, therefore, Dr. Baxter would presumably be precluded from working with virtually every doctor and hospital in the country.

delivery of an item or service under Medicare or Medicaid whenever a misbranded drug is introduced "into interstate commerce" and the misbranded drug "is paid for by Federal and State health care programs." AR011, AR013; *see* AR032–35.[6] That erroneous construction would vastly expand the Secretary's power, permitting him to subject virtually every instance of misbranding to mandatory exclusion. It would also eviscerate the scheme actually enacted by Congress by rendering section 1128(b) a nullity, thereby infringing on due process rights by eliminating the Secretary's ability to consider mitigating circumstances in determining whether exclusion is appropriate.

B. Section 1128(a)(1) Does Not Encompass RCO Misdemeanor Misbranding.

Because the Secretary's position implicates serious questions regarding his statutory authority, this Court may only uphold it if it finds "clear congressional authorization" for his claimed authority. *Nat'l Fed'n of Indep. Bus.*, 142 S. Ct. at 665; *see West Virginia*, 142 S. Ct. at 2605. Such clear authorization plainly is lacking here, as section 1128(a)(1) is best read to foreclose the Secretary's position that the provision encompasses a strict-liability misdemeanor misbranding offense under the RCO doctrine. At the very least, the statute is ambiguous and thus cannot support the Secretary's expansive claim.

In this case, the Secretary excluded Dr. Baxter under section 1128(a)(1) based upon his determination that Dr. Baxter's misdemeanor misbranding conviction under the RCO doctrine was "a criminal offense related to the delivery of an item or service under a state health care program." AR033 (citing 42 U.S.C. § 1320a-7(a)(1)). The statute, however, simply cannot bear such a

[6] On appeal within the agency, the Secretary essentially confessed that this position is legal error by making the unsupported assertion that "[t]he ALJ did not conclude that mandatory exclusion is required whenever one introduces a misbranded drug into interstate commerce that is paid for by a federal or state health care program." AR040. But that is exactly what the agency did, as neither the ALJ nor the Board identified any actual delivery of Suboxone Film under the MassHealth program—let alone delivery that is in any way attributable to the misbranding.

reading. Misdemeanor misbranding (under the RCO doctrine or otherwise) is a Title 21 offense that makes no reference to, and does not inherently involve, any federal or state health care program. *See* 21 U.S.C. §§ 331(a), 333(a)(1); 352(a).

That misdemeanor misbranding does not inherently involve a covered program is undisputed. That is precisely why the Secretary has adopted (in prior litigation and in the proceeding below) a position seemingly untethered to any statutory authority and incongruent with congressional intent. Specifically, the Secretary has rejected a "categorical approach" in favor of a "'circumstance-specific' approach" that "'look[s] to the facts and circumstances underlying an offender's conviction' to determine whether that conviction is covered by the statute." *Friedman*, 686 F.3d at 819 (upholding circumstance-specific approach with respect to permissive exclusion). In his administrative proceedings, the Secretary "has repeatedly held that the basis for an exclusion stems from the nature and circumstances of the underlying conviction, not the label or even the elements of the crime." AR043.

The problem with the Secretary's approach is that it expands the statute far beyond Congress's intent. According to the Secretary, he is not constrained by the necessary elements of a conviction but may sift the record and apply "common sense" to determine whether, in his view, there is a "connection" or "nexus" "between the offense and the delivery of an item or service under the program." AR032. This "test" does not actually "illuminate the factors that properly go into whether th[e] conviction meets the statutory requirement" but leaves exclusion subject to the Secretary's discretion, which is inappropriate for mandatory exclusion. *Kabins v. Sebelius*, No. 2:11-cv-01742-JCM, 2012 WL 4498295, at *3 n.1 (D. Nev. Sept. 28, 2012); *see ibid.* ("[G]iven that what 'common sense' dictates can vary so significantly from person to person, a 'common sense' test is either likely meaningless as a decisional tool or so susceptible to inconsistent application as to be arbitrary and capricious."). That was evident below, where the Secretary

repeatedly sought to distinguish contradictory precedent based upon shifting and immaterial factual differences among cases. AR040–044. Under that approach, the Secretary can sweep into section 1128(a)(1) crimes that do not satisfy the terms of the statute—as he did here by subjecting Dr. Baxter to exclusion for a strict-liability application of misdemeanor misbranding.

For that reason, at least one federal district court has expressly rejected the Secretary's circumstance-specific approach. There, the court reversed and vacated the mandatory exclusion of a physician from all federal health care programs under section 1128(a)(3) because "no element of the crime" "include[d] delivery of health care as a necessary requirement." *Kabins*, 2012 WL 4498295, at *3; *see* 42 U.S.C. § 1320a-7(a)(3) (mandating exclusion for "a criminal offense consisting of a felony relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct" "in connection with the delivery of a health care item or service"). Rejecting the Secretary's claim that she was entitled to rely on the "facts and circumstances" of the physician's conviction, Def.'s Mot. Summ. J. at 22, *Kabins* (No. 2:11-cv-01742-JCM, ECF No. 16), the court explained "that giving such breadth to the mandatory exclusion statute increases considerably the risk of selective enforcement of the exclusion sanction, targeting those defendants where the prosecuting authority and investigating agency may feel the criminal penalty was insufficient or was prematurely terminated," *Kabins*, 2012 WL 4498295, at *3.

In addition, federal appellate courts have held that similar statutory language mandates the categorical approach. For example, the Immigration and Naturalization Act ("INA") makes an alien deportable if he has been convicted of a crime "relating to" a controlled substance. 8 U.S.C. § 1227(a)(2)(B)(i). To make that determination, courts are not permitted to look beyond the generic offense for which the alien had been convicted—*i.e.*, courts have held that the statutory language mandates the categorical approach. *See Bah v. Barr*, 950 F.3d 203, 211 (4th Cir. 2020) (holding alien deportable based on "a categorical match"); *Castaneda de Esper v. INS*, 557 F.2d

79, 81–84 (6th Cir. 1977) (similar). Despite the presumption that identical statutory phrases "are presumed to have consistent meaning throughout the U.S. Code," Antonin Scalia & Bryan Garner, *Reading Law: The Interpretation of Legal Texts* 172 (2012), the Secretary has adopted a discordant reading of this phrase in section 1128(a)(1).

For these reasons, this Court should hold that "a criminal offense related to the delivery of an item or service under [Medicare] or under [Medicaid]," 42 U.S.C.§ 1320a-7(a)(1), includes only a crime that by its terms involves the delivery of an item or service under Medicare or Medicaid. At the very least, the Court should hold that the statutory language is ambiguous and thus cannot encompass a strict-liability, no intent misdemeanor misbranding offense under the RCO doctrine. Because "criminal offenses requiring no *mens rea* have a generally disfavored status," *Liparota*, 471 U.S. at 426 (internal quotation marks omitted), due process insists that "penalties" for these crimes be "relatively small," so that "conviction does no grave damage to an offender's reputation," *Morissette*, 342 U.S. at 256. Here, where it is undisputed that Dr. Baxter's offense cannot qualify for exclusion absent the Secretary's dubious interpretation of the facts underlying his conviction, Dr. Baxter should not be subjected to mandatory exclusion under section 1128(a)(1).

C. Dr. Baxter's Offense Qualifies, At Most, For Permissive Exclusion.

For the reasons identified above, Dr. Baxter cannot be subject to mandatory exclusion under section 1128(a) using the categorical approach. But even under the Secretary's approach, Dr. Baxter's offense at most qualifies for permissive exclusion as "a misdemeanor relating to fraud." 42 U.S.C. § 1320a–7(b)(1)(A). And if Dr. Baxter's conduct is subject to permissive exclusion, then "the mandatory provision is inapplicable." *Leddy v. Becerra*, No. 22-cv-425, 2022 WL 2978620, at *6 (E.D.N.Y. July 28, 2022) (enjoining mandatory exclusion where permissive exclusion applied).

As the *Leddy* court explained, the conclusion that an offense cannot be subject to both mandatory and permissive exclusion "derives from . . . '[t]he ancient interpretive principle that the specific governs the general (*generalia specialibus non derogant*)." 2022 WL 2978620, at *6 (quoting *Nitro-Lift Techs., L.L.C. v. Howard*, 568 U.S. 17, 21 (2012)). Under that principle, "when two statutes cover the same situation, the more specific statute takes precedence over the more general one." *Ibid.*; *see also United States v. Grant*, 715 F.3d 552, 558 (4th Cir. 2013) ("a specific statute closely applicable to the substance of the controversy at hand controls over a more generalized provision" (citation omitted)).

Here, the application of section 1128(b)(1) is more specific than the overly broad construction the Secretary has afforded section 1128(a)(1). It is undisputed that a misdemeanor misbranding offense under the RCO doctrine is not inherently program related, so there is clearly no relationship under the categorical approach. And Dr. Baxter's offense is not program related under the circumstance specific approach either because, as explained in section II.B., *infra*, the Secretary failed to identify a single delivery of Suboxone Film attributable to the misbranding and MassHealth offered Suboxone Film prior to the misbranding and continued to expand access to the drug after the misbranding was disclosed. Permissive exclusion more specifically addresses Dr. Baxter's offense under either approach because it enacts "Congress' intent that an individual *may* be excluded from the Medicare and Medicaid programs" for misconduct that "had nothing to do with Medicare or Medicaid." *Travers*, 801 F. Supp. at 404–05 (emphasis in original).

But there is no need to take Dr. Baxter's word for it. The Secretary has previously determined that misdemeanor misbranding under the RCO doctrine is "a misdemeanor relating to fraud" subject to permissive exclusion. In *Friedman v. Sebelius*, 686 F.3d 813 (D.C. Cir. 2012), the Secretary excluded three pharmaceutical executives under section 1128(b)(1) where their employer, Purdue Frederick Company, had been convicted of felony misbranding in violation of

21 U.S.C. §§ 331(a) and 333(a)(2), and the executives had pled only to misdemeanor misbranding under §§ 331(a) and 333(a)(1) pursuant to the RCO doctrine. *See id.* at 816.

In *Friedman*, the underlying conduct involved "misrepresentations certain unnamed Purdue employees made regarding OxyContin." *Id.* at 817. Deferring to the Secretary's circumstance-specific approach, the court held that this offense need not "share all the 'core elements' of fraud" to constitute "a misdemeanor relating to fraud" so long as there was at least some "factual relationship between the conduct underlying the misdemeanor and the conduct underlying a 'fraud.'" *Id.* at 820–21.[7] Furthermore, the facts showed that "Purdue had almost $3 billion in revenues from OxyContin during the time it misbranded the drug, *much of it from Federal and state health care programs which paid for prescriptions for OxyContin.*" *Id.* at 825 (emphasis added).

Here, just like the executives in *Friedman*, Dr. Baxter was convicted of RCO misdemeanor misbranding under 21 U.S.C. §§ 331(a) and 333(a)(1). AR0549. And here, also just like *Friedman*, that conviction was said to rest on "false and misleading statements" by other persons who supposedly advantaged the company financially. AR545, AR623. But unlike the executives in *Friedman*, in this case the Secretary charged Dr. Baxter with mandatory rather than permissive exclusion, thereby foreclosing his ability to consider mitigating circumstances when determining the length of Dr. Baxter's exclusion—or even whether any length of exclusion was appropriate. *Compare* 42 U.S.C. § 1320a–7(c)(3)(B) (five-year mandatory minimum exclusion) *with id.* § 1320a–7(c)(3)(D) (three-year presumptive exclusion with opportunity to mitigate).

[7] The *Friedman* court did not embrace the circumstance-specific approach with respect to mandatory exclusion and, as discussed *supra*, the *Kabins* court rejected it in that context.

The rest of section 1128(b) confirms that if Dr. Baxter's conduct fits anywhere, it is under permissive exclusion. Section (b)(3) authorizes permissive exclusion for a person convicted of "a misdemeanor relating to" certain acts involving "a controlled substance," 42 U.S.C. § 1320a–7(b)(3), and in *Friedman* the Secretary argued this provision encompasses misbranding, 686 F.3d at 818 n.* ("we do not pass upon the parties' dispute over whether the Appellants could be excluded pursuant to section (b)(3)"). Similarly, section (b)(16) authorizes permissive exclusion for a person convicted of making "any false statement, omission, or misrepresentation of a material fact" in some circumstances "under a Federal health care program." 42 U.S.C. § 1320a–7(b)(16). Even if section (b)(16) is not directly applicable here, it provides further evidence that Congress believed misrepresentations were more appropriate for permissive exclusion than mandatory exclusion even when they could conceivably be characterized as program-related.

Because, if anything, section 1128(b) governs this case, Dr. Baxter cannot be subject to mandatory exclusion. *Leddy*, 2022 WL 2978620, at *6 (enjoining mandatory exclusion under section 1128(a)(1) where permissive exclusion under section 1128(b)(2) applied); *see also Travers*, 801 F. Supp. at 404 (recognizing mandatory and permissive exclusion are mutually exclusive). Thus, the Secretary has exceeded his authority even under the circumstance-specific approach.

* * * * *

In sum, the Court should vacate the Secretary's decision. Section 1128(a)(1) does not authorize the Secretary to impose on Dr. Baxter the career-destroying penalty of mandatory exclusion from all federally-funded health care programs for five years based solely on pleading guilty to a single, strict-liability misdemeanor misbranding offense under the RCO doctrine. To the contrary, the best reading of section 1128(a)(1) is that it affirmatively forecloses that result. At the very least, the Court should vacate and require the Secretary to reassess whether Dr. Baxter

should be permissively excluded under section 1128(b) and the length of his exclusion shortened in light of the extensive mitigating circumstances that were present here.

II. THE SECRETARY'S EXCLUSION OF DR. BAXTER WAS OTHERWISE ARBITRARY AND CAPRICIOUS.

At bottom, the text of section 1128 simply cannot sustain the Secretary's expansive construction. The Secretary's longstanding practice makes that clear. But even if Congress had directed the Secretary to treat some misdemeanor misbranding offenses under the RCO doctrine as warranting mandatory exclusion, his decision to do so here was arbitrary and capricious. *See* 5 U.S.C. § 706(2).

A. Mandatory Exclusion Is An Unjustified Departure From HHS Practice.

The Secretary's decision to exclude Dr. Baxter was a departure from "longstanding regulatory practice." *Cnty. of Maui v. Hawaii Wildlife Fund*, 140 S. Ct. 1462, 1472 (2020). For at least three reasons, this unacknowledged and "unexplained[,] inconsistency in agency policy indicates that the agency's action is arbitrary and capricious, and therefore unlawful." *Jimenez-Cedillo v. Sessions*, 885 F.3d 292, 298 (4th Cir. 2018) (citation omitted).

First, the Secretary failed to justify his departure from the practice endorsed in *Friedman*. There, as explained, the Secretary successfully defended his "longstanding interpretation" "of 'related to,'" Appellees Br. 12, *Friedman* (No. 11-5028, Doc. #1339653), which resulted in strict liability convictions for RCO misdemeanor misbranding becoming subject to permissive exclusion because they were based on "misrepresentations" about a drug subsequently "paid for" by "Federal and state health care programs," *Friedman*, 686 F.3d at 817, 825. That, of course, is exactly what the Secretary claims happened in this case. *See* Section I.C. *supra*.

Nevertheless, the Secretary purports to distinguish *Friedman* and subject Dr. Baxter to mandatory exclusion on the ground that *Friedman* "involved the delivery of a misbranded drug

without regard to any particular health care program." AR043-44. But that is not what the Secretary told the D.C. Circuit. There, she claimed that "[a]mple record evidence supports the Secretary's finding that the conduct underlying the Purdue Executives' convictions caused losses" to health care programs run by "federal and state governments." Appellees Br. 48, *Friedman* (No. 11-5028, Doc. #1339653). And the court agreed, finding that "approximately $160 million [of a $600 million financial penalty] was earmarked for restitution to Federal and State health care agencies, which had been large buyers of the misbranded drug," and declaring that section 1128(b)(1) was designed "to protect Federal health care programs from financial harm wrought by untrustworthy providers." *Friedman*, 686 F.3d at 816, 820. Given these circumstances, the Secretary's claim that *Friedman* is distinguishable because it supposedly did not involve a particular health care program is wholly unpersuasive.

Second, the Secretary failed to justify his application of mandatory exclusion in the absence of any restitution payment by Dr. Baxter. For decades, the Secretary has required evidence of a restitution payment or forfeiture order before concluding that a conviction for misdemeanor misbranding was "program related." *See, e.g.*, *Schmidt*, DAB CR3746, at 9 (2015) ("In exclusion cases, restitution has long been considered a reasonable measure of program loss and evidence of the nexus between the offense and the program to which restitution is to be made."). Here, the record shows that Dr. Baxter was not required to forfeit funds or pay restitution.

Confronted with his change in policy, the Secretary responded below with a non-sequitur: "the I.G. has, on numerous occasions, excluded individuals convicted of misdemeanor drug misbranding offenses under section 1128(a)(1) of the Act." AR043. *But see* AR042 (claiming "I.G. exclusion determinations are not 'precedent'"). No one disputes that point, and the examples the Secretary cites all prove Dr. Baxter's point as each involved mandatory exclusion *after a court-ordered restitution payment*. *See Parrino*, DAB CR3287 (2014) (restitution of $14,098.24);

Miranda, DAB CR3755 (2016) (restitution of over $1 million); *Aswad*, DAB CR2741 (2016) (restitution of over $1 million); *Keegan*, DAB CR3242 (2014) (restitution of over $2 million); *Koh*, DAB CR5262 (2019) (restitution of $250,000); *cf. Hoffmeister*, DAB CR3973, at 2–3 (2015) ("*Based on Petitioner's restitution* and the records from his underlying conviction, I find Petitioner's criminal offense and subsequent conviction relate directly to his delivery of podiatry services under Medicare." (emphasis added)).[8] After multiple rounds of briefing, the Secretary remains unable to offer a single authority (from his own precedent or otherwise) supporting the assertion that he has previously construed section 1128(a)(1) to reach a misdemeanor misbranding offense in the absence of a restitution payment. His decision to exclude Dr. Baxter absent restitution thus represents an unacknowledged change in policy.

Contrary to the Secretary's contention, Dr. Baxter's emphasis on restitution is not an "attempt[ ] to read into section 1128(a)(1) conditions and limitations that do not exist under the plain language of the statute." AR044. Dr. Baxter is merely insisting that "[t]he treatment of cases A and B, where the two cases are functionally indistinguishable, must be consistent." *Indep. Petroleum Ass'n v. Babbitt*, 92 F.3d 1248, 1260 (D.C. Cir. 1996); *see FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) ("the requirement that an agency provide reasoned explanation for its action would ordinarily demand that it display awareness that it *is* changing position"). The Secretary appears to dislike this fundamental precept of administrative law, *see* AR042 ("the I.G.'s enforcement actions against other individuals under other circumstances have no bearing on whether the I.G. had a valid basis to exclude Petitioner"); AR015 (similar), but that does make it any less enforceable.

[8] The lone exception is *Thaxter*. But again, that only underscores the recent change in policy as *Thaxter* was litigated parallel to this case.

Finally, the lack of any restitution payment undermines the statutory basis for mandatory exclusion even apart from the Secretary's unacknowledged and unexplained change in policy. Had the district court believed that the conduct for which Dr. Baxter was convicted resulted in the delivery of a drug under MassHealth, then it almost certainly would have required Dr. Baxter to pay restitution. But the court did not do so, and the presentence report indicated that there were *no losses or victims associated with Dr. Baxter's conduct*. *See* Presentence Investigation Report at 9, 14, *United States v. Baxter*, No. 1:20-cr-32 (W.D. Va. Dec. 14, 2020), ECF No. 25. The lack of any restitution payment is thus further evidence that Dr. Baxter's offense was unrelated to MassHealth, and that the Secretary's decision to exclude Dr. Baxter under section 1128(a)(1) was arbitrary and capricious.

B. Mandatory Exclusion Is Unsupported By The Record.

The Secretary's decision must also be set aside because it is "not justified by the [administrative] record." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983). The Information identifies as the relevant MassHealth decision a December 2012 prescriber letter that informs prescribers and health care providers that MassHealth had expanded access to Suboxone Film. AR546–47. That letter states that MassHealth would adjust its approval criteria for prior authorization requests submitted on behalf of MassHealth "members prescribed Suboxone who live in households with children less than six years of age." AR440.

To justify that decision, the letter cites only accurate, nationwide published RADARS data "document[ing] a greater unintentional exposure risk of buprenorphine/naloxone tablets than with that of the film in children 0 to five years of age." AR440. The letter does not cite any inaccurate or misbranded information. It is axiomatic that "in reviewing agency action, a court is ordinarily limited to evaluating the agency's contemporaneous explanation in light of the existing administrative record." *Dept. of Com. v. New York*, 139 S. Ct. 2551, 2573 (2019). Because

MassHealth's contemporaneous explanation for its expansion decision relied on accurate information and not on any misbranded information, the expansion decision was not "related to" the offense for which Dr. Baxter accepted responsibility. The record thus does not support mandatory exclusion under section 1128(a)(1).

Seeking to bridge the chasm, the Secretary cited testimony taken in a different proceeding involving a different defendant. There, Dr. Jeffrey stated that had the (accurate) chart Dr. Ruby sent him included a third line of data for Subutex Tablets "it would have signaled that I needed to look at the data that was presented to me differently." AR693; *see* AR023. And the Secretary highlights Dr. Jeffrey's remark that receipt of the inaccurate Massachusetts-specific was data was "the 'pivot point' on which MassHealth changed its policy" around Suboxone Film. AR037. But these statements do not establish the requisite nexus.

As the threshold, the Secretary erred in admitting them because Dr. Baxter had no opportunity to cross-examine Dr. Jeffrey as is his "right[ ]." 42 C.F.R. § 1005.3(a)(6); *see Wallace v. Bowen*, 869 F.2d 187, 193-94 (3d Cir. 1989) (holding "there was no waiver . . . of the right to cross-examination" where claimant did "not request[ ] that the ALJ subpoena the two physicians for cross-examination"); *Mase v. Comm'r of Soc. Sec.*, No. CV 21-10024, 2022 WL 1184801, at *3 (D.N.J. Apr. 21, 2022) ("[W]hen an administrative law judge chooses to go outside the testimony adduced at the hearing in making a determination . . . , the ALJ must afford the claimant not only the opportunity to provide comment and present evidence but also the opportunity to cross-examine[.]"). As the Secretary bears the burden of proving exclusion, it was incumbent on him to call Dr. Jeffrey if he intended to rely on his testimony, and thus to subject him to potential cross.

In all events, Dr. Jeffrey's testimony confirms that MassHealth's expansion decision was unrelated to the misbranding. Dr. Jeffrey stated that "ultimately we made a change in our policy

around Suboxone Film. And this was the pivot point upon which we made that decision." AR690. When asked to clarify what he meant, Dr. Jeffrey said: "if the exposure to the film was greater than the exposure of the tablets, then it—you know, again, I would have stopped any process to change our policy decision around the film." AR691. But the exposure to the film was not, in fact, greater than the exposure to the tablet, Lavonas, *supra* note 2, and Dr. Jeffrey repeatedly refused to say that Dr. Ruby's presentation of the data had any effect on MassHealth's decision to expand coverage of Suboxone Film. AR691 ("I don't know if it would have made a change in the decision."); *see* AR544, AR546. Thus, far from supporting mandatory exclusion, Dr. Jeffrey's testimony underscores that Dr. Baxter's offense is unrelated to MassHealth's decision to expand coverage of Suboxone Film.

Furthermore, the expansion decision did not result in "delivery" of Suboxone Film, as is required by section 1128(a)(1) to authorize exclusion. The record shows "Suboxone Film was available through MassHealth prior to December 2012." AR005; *see also* AR495, AR542. Although the 2012 expansion decision softened the prior authorization requirements for households with children under six years old, the Secretary failed to establish that MassHealth actually "paid for prescriptions for [Suboxone Film], some of which would not have been written *but for the misbranding*." *Friedman*, 686 F.3d at 825 (emphasis added).

Indeed, MassHealth's own actions show that any theoretical deliveries were unrelated to Dr. Baxter's offense. In January 2016—that is, soon after Dr. Baxter had "approved sending a correction letter to MassHealth" identifying the company's previously inaccurate representations, AR0547—MassHealth again promoted Suboxone Film, this time to be the "preferred buprenorphine/naloxone product" for all MassHealth beneficiaries and to generally eliminate the prior authorization requirement. AR447. Today—despite years of litigation focusing on the

misbranding—Suboxone Film is still MassHealth's preferred drug. AR499, AR522, AR524.[9] *Cf. United States v. Strock*, 982 F.3d 51, 60 (2d Cir. 2020) (rejecting "materiality analysis that prioritizes the government's claims about how it would treat a requirement over how the government actually treats a requirement upon discovering a violation.").

On this record, it was arbitrary for the Secretary to conclude that MassHealth's 2012 expansion decision was "related to" the offense for which Dr. Baxter accepted responsibility. For similar reasons, it was arbitrary for the Secretary to conclude that any "delivery" of Suboxone Film under the MassHealth program was attributable to the expansion decision. Thus, the record does not support mandatory exclusion under section 1128(a)(1).

CONCLUSION

This Court should grant summary judgment for Dr. Baxter, set aside the decision below as arbitrary, capricious, and contrary to law, and remand to the agency with instructions to vacate the exclusion.

Dated: March 8, 2023

/s/ Brandon J. Moss

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[9] Although the Secretary purported to exclude both the "MassHealth notice regarding Suboxone Film's preferred status in January 2016" and the "MassHealth preferred drug list including Suboxone Film in February 2022" from the evidence, AR025–26, they remain a part of the administrative record and this Court may, in all events, "take judicial notice of public and government documents," *Sierra Club v. EPA*, No. 21-3057, __ F. 4th ___, 2023 WL 1873168, at *3 n.2 (6th Cir. Feb. 10, 2023); *see, e.g.*, *Virginia Innovation Scis., Inc. v. Samsung Elecs. Co.*, 983 F. Supp. 2d 700, 707 (E.D. Va. 2013) (taking judicial notice of government document).